K081889

1 of 2

510(K) SUMMARY
(as required by 807.92(c))

NOV 12 2008

Submitter of 510(k): GrantAdler Corporation
1733 Park Street Suite 104
Naperville, IL 60563
USA

Phone: 800-605-4815
Fax: 773-442-0992

Contact Person: Michael Loiterman

Date of Summary: 11/4/08

Trade/Proprietary Name: Rhapsody CT

Classification Name: Port & catheter, implanted, subcutaneous, intravascular

Product Code: LJT

Intended Use:
The Grant Adler Rhapsody port line is intended to facilitate reliable and repeated acces of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products or the sampling of blood. Access is performed by percutaneous needle insertion, using only non-coring, Huber needles. When used with a power injectable needle, Rhapsody CT is indicated for power injection of contrast media. For power injection of contrast media, the maxum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle and 2 ml/s with 22 gauge non-coring power injectable needle. The Rhapsody CT has been tested and is conditionally safe to use in an MRI environment up to 3T.

Device Description:
The Rhapsody CT is supplied as a sterile device, and is intended for single patient usc only. The port is available as a single model and is manufactured of the highest quality titanium. It also incorporates a durable high compression self-sealing silicone septum. Catheter materials include flexible, non-compressible, and reinforced silicone. The Port is normally inclused in a Convenience Kit which will be used for the procedure. The GrantAdler Convenience Kit includes all cleared or exempt devices.

Predicate Device:
K060812 - Bard Inc - PowerPort™ Implanted Titanium Port with 8 Fr. ChronoFlex® Catheter
K043178 - GantAdler Rhapsody Access Port and Catheter

K081559
2 of 2

Grant Adler Rhapsody CT
Table of Comparison

Test Description	Rhapsody CT	Grant Adler Rhapsody K043178	Bard Power Port K060812
Indications for Use	Power Injection	No Power Injection	Power Injection
Labeling	Equivalent	Equivalent	Equivalent
Target Population	Equivalent	Equivalent	Equivalent
Hospital Use	Yes	Yes	Yes
Design	Port with Septum	Equivalent	Equivalent
Materials, Port	Titanium	Titanium	Titanium
Materials, Septum	Silicone NuSil MED-4780	Silicone NuSil MED-4780	Silicone
Materials Catheter	Silicone NuSil MED-4780	Silicone NuSil MED-4780	Silicone
Dimensional	28.3mm x 12.7mm	Identical	32mm x 12.8mm
Catheter to Port Connection	Double Barbed Fitting	Double Barbed Fitting	Barbed Fitting
Septum Puncture	Needle	Needle	Needle
Port Leak Testing	No Leaks	Equivalent	Equivalent
Sterilization Information	ETO	ETO	ETO
Biocompatibility Assessment	Pass	Pass	Pass
Catheter	7 Fr. up to 52cm	Identical	8 Fr. up to 45cm
Max Power Injection Flow	5ml/s 19 AWG	N/A	5ml/s 19 AWG
Max PI Pressure	Less than 300 psi	N/A	Less than 300 psi
MRI Safe	Yes	510k in process	Unknown

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2008

GrantAdler Corporation
C/O Arthur J. Ward, Ph.D.
AJW Technology Consultants, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K081889
Trade/Device Name: Rhapsody CT
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: November 4, 2008
Received: November 5, 2008

Dear Dr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susette G. Michaud MD
FOR DR. CHIU LIN

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081889
1 of 1

Indications for Use

510(k) Number (if known): K081889

Device Name: Rhapsody CT

Indications for Use:

The Grant Adler Rhapsody port line is intended to facilitate reliable and repeated acces of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products or the sampling of blood. Access is performed by percutaneous needle insertion, using only non-coring, Huber needles. When used with a power injectable needle, Rhapsody CT is indicated for power injection of contrast media. For power injection of contrast media, the maxum recommended infusion rate is 5 ml/s with a 19 or 20 gauge non-coring power injectable needle and 2 ml/s with 22 gauge non-coring power injectable needle. The Rhapsody CT has been tested and is conditionally safe to use in an MRI environment up to 3T. The Port is normally included in a Convenience Kit which will be used for the procedure. The GrantAdler Convenience Kit includes all cleared or exempt devices.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081889

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)